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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,014	07/31/2003	Christopher J. Calhoun	MA9606P	9368

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,014	CALHOUN ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11192009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Receipt

Applicant's response filed on 10/13/2009 to the Office Action mailed on 05/13/2009 is acknowledged.

Status of the Claims

Claims 1-6, 14, 19, 21, 34 and 36 are currently amended and claims 30-33 and 37-51 are cancelled. Therefore, claims 1-29 and 34-36 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims

2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 2, 4-29, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakker et al. (US Patent 5508036, Published 04/16/1996).

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly -lactide having a thickness of about 0.01 to about 0.300 mm surrounding an implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Bakker et al. teach, "A device for preventing adhesions or binding of tissue to tissue or tissue to bone which comprises a composite of a first layer and a second layer, each of which comprises a biodegradable polymer. The first layer is selected from the group consisting of a non-porous layer and a porous layer having a pore size no greater than 3μ." (See abstract). "The first layer is a 'dense' layer which acts as a barrier layer and which is non-porous (i.e. the layer essentially has no pores) or if porous, essentially all of the pores have a pore size no greater than 3μ. Preferably, the first layer is non-porous. Also, the first layer preferably has a high water content. The first layer, in general, also prevents the ingrowth of tissue. In general, the first layer has thickness

from about 5μ to about 80μ, preferably from about 15μ to about 50μ." (See column 1, Lines 59-68). "Polymers which may be employed to form the first and second layers of the composite device include, but are not limited to .... polylactides, such as, for example polylactic acid ... In one embodiment, the polymer may be a copolymer formed from any combination of the above components." (See column 3, Lines 15-33). "Alternatively, the second, or porous, layer of the device may be replaced with a layer which adheres to tissue or bone such that the device effectively prevents the binding of tissue to tissue or tissue to bone." (See column 12, Lines 20-31). "The second, or adherence layer, may be formed from one or more adhesives such as, but not limited to, cellulose .... mucoadhesive ...." (See column 12, Lines 40-50). "The devices of the present invention may also be used for guided tissue regeneration." (See column 11, Lines 19-20).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Bakker et al. teach in perferred embodiments that the non-porous first layer is preferably made of co-polymer of PEGT and PBT but lacks a preferred embodiment wherein the nonporous layer is made from a polylactide polymer. However, Bakker et al. does make such a first layer obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to form the first layer of the anti-adhesive device taught by Bakker et al. with polylactide polymers. One would have been motivated to do this because Bakker et al. teach that the first layer may be formed from polylactides such as polylactic acid or copolymers of polylactides. Combining prior art elements according to known methods to yield predictable results, absent unexpected results, would have been obvious to one of ordinary skill in the art. With regard to the limitation applying the membrane to an implant, the Examiner has interpreted the adhesive layer of the device taught by Bakker et al. reads on "wherein the medical device comprises one or more of tissue glues and adhesives" in claim 17, and therefore the composite device taught by Bakker et al. teach applying a lactide polymer membrane to an implant. With regard to the limitation, "a property of resorbing from more than 6 months to 24 months and a viscosity property from more than about 1 g/dL to 3.5 g/dL", it is the Examiners position that the polymer layer taught by Bakker et al. and the instantly claimed membrane are structurally indistinguishable. Therefore, the aforementioned properties are implicit to the polymer layer taught by Bakker et al. For the foregoing reasons, the instant methods would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakker et al. (5508036, Published 04/16/1996) in view of Massie et al. (Anti-Fibrotics in the prevention of epidural fibrosis: Gels versus a barrier sheet, Published 2001) as evidenced by Welch et al. (Use of polylactide resorbable fim as an adhesion barrier, Published 11/2002).

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide having a thickness of about 0.01 to about 0.300 mm surrounding an implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Bakker et al. are discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Bakker et al. does not teach a first layer consisting essentially of poly-L-lactide and poly-D-L-lactide. This deficiency is cured by the teachings of Massie et al.

Massie et al. teach a 70:30 poly-L-lactide and poly-D-L-lactide barrier sheet for insertion into between the dural sleeve and the paravertebral musculature post laminectomy. (See Introduction).

Welch et al. teach that the barrier sheet taught in Massie et al. is a 0.2mm-tick resorbable non-porous film. (See page 414, column 1, Lines 32-58 and column 2, Lines 25-40).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Bakker et al. with Massie et al. One of ordinary skill in the art at time of the instant invention to use the barrier sheet of Massie et al. in device of Bakker et al. in order to provide an anti-adhesive implant for use in back surgery. For the foregoing reasons, the instant methods would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616